

REMARKS

Favorable reconsideration of this application, as amended, is respectfully requested. Claims 9-32 are currently pending.

At page 2 of the Office Action, the drawings are objected to because FIG. 26 does not contain the reference character "c" as described in the brief description of the drawing. Responsive to this objection, enclosed with this amendment is a replacement sheet for FIG. 26 that includes the missing reference character "c."

At page 3 of the Office Action, the specification has been objected to because of the following informalities: (1) a blank reference to the provisional application that was filed April 15, 2004; and (2) this April 15, 2004 provisional application is not provided in the filed oath/declaration. Responsive to this objection, paragraph [01] at page 1 of the above application has been amended to provide the Serial No. (60/562,324) for this April 15, 2004 provisional application. Also enclosed in response to this objection is a supplemental application data sheet that references this April 15, 2004 provisional application and claims the benefit of the filing date thereof. In addition, a supplemental oath/declaration of the Applicants that references this April 15, 2004 provisional application and claims the benefit of the filing date thereof is currently in progress and will be submitted as a supplemental response.

At page 3 of the Office Action, Claims 1 and 14-17 have been objected to because the term "*piggyBac*" has misspelled. Responsive to this objection, and without disclaimer or prejudice, Claim 1 has been rewritten as new Claim 20, and Claims 14-17 have been amended to correct the misspelling of this term. In addition, paragraph [15] at page 4, paragraph [148] at page 38, and paragraph [166] at page 40 of the above application have been amended to correction similar misspellings of this term.

Claims 1-8 have been rewritten as new Claims 20-27. Support for new Claims 20-27 can be found from a combined reading of FIG. 25 of the drawings, as well as paragraph [29] at page 10, paragraph [33] at page 10, paragraphs [41]-[45] at pages 12-13, paragraph [48] at page 14, paragraph [97] at pages 27-28, and paragraph [109] at page 32, of the above application. In view of new Claims 20-27, Claims 14-15 have been amended accordingly.

New Claims 28-32 have also been added. Support for new Claims 27-31 can be found from a combined reading of FIG. 25 of the drawings, as well as paragraph [29] at

page 10, paragraph [33] at page 10, paragraph [35] at page 11, paragraphs [41]-[45] at pages 12-13, paragraph [48] at page 14, paragraph [97] at pages 27-28, and paragraph [109] at page 32, of the above application.

A. Response to Rejection of Claims 1-8 under 35 U.S.C. 101 as Being Directed to Non-Statutory Subject Matter

At pages 3-4 of the Office Action, Claims 1-8 have been rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Specifically, the Office Action alleges that these Claims encompass a DNA molecule that reads on the *piggyBac* molecule (also alleged to be known as the IFP2 transposon). The Office Action further alleges that the *piggyBac* transposon is found in nature in the genome of the cabbage looper moth, *Trichoplusia ni*. The Office Action further suggests it would be remedial to insert the term “isolated” in connection with the DNA to indicate that the DNA is a product not found in nature.

Responsive to this rejection, Claims 1-8 have been rewritten as new Claims 20-27 which define DNA molecules comprising a minimal transposable *piggyBac* genetic construct. As defined in paragraph [33] at page 10 of the above application, the term “genetic construct” refers to any artificially assembled combination of DNA sequences. Accordingly, the subject matter of new Claims 20-27 cannot be found in nature, and is therefore statutory subject matter under 35 U.S.C. 101.

B. Response to Rejection of Claims 1-8, 14-15 and 18-19 under 35 U.S.C. 112, Second Paragraph, as Being Indefinite

At page 4 of the Office Action, Claims 1-8, 14-15 and 18-19 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the term “said region” in line 4 of Claim 1 is objected to.

Responsive to this rejection, Claims 1-8 have been rewritten as new Claims 20-27 without the phrase “said region” that was objected to. Claims 14-15 and 18-19 have also been amended to depend from new Claims 20 or 23. Accordingly, new Claims 20-27, as written, as well as Claims 14-15 and 18-19, as amended, overcome this rejection under 35 U.S.C. 112, second paragraph.

C. Response to Rejection of Claims 10, 12-13 and 17 under 35 U.S.C. 112, First Paragraph, for Lack of Enablement

At pages 4-6 of the Office Action, Claims 10, 12-13 and 17 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Office Action alleges that the cartridges and vectors defined by these Claims are encompassed by the definitions of “biological material” set forth in 37 CFR 1.801. The Office Action further alleges that it is unclear whether this “biological material” (*i.e.*, the ITR1.1k of Claims 10 and 17, and the pXL-BacII-ECFP and pBSII-ITR1.1k-ECFP of Claims 12 and 13) are known and readily available to the public, or that the written description is sufficient to reproducibly construct this “biological material.”

Applicants respectfully traverse this rejection with regard to Claims 10, 12-3 and 17, especially as amended. Responsive to this rejection, Claim 10 has been amended to clarify that the ITR1.1k construct is shown in FIG. 25. Contrary to what the Office Action suggests, and as shown in FIG. 25 of the drawings, as well as the corresponding written description in paragraph [97] at pages 27-28, and paragraph [109] at page 32, the above application more than adequately describes to one skilled in the art how to prepare the ITR1.1k, pXL-BacII-ECFP and pBSII-ITR1.1k-ECFP constructs of the cartridges and vectors of Claims 10, 12-13 and 17, in accordance with 35 U.S.C. 112, first paragraph. Therefore, the written description in the above application is sufficient to reproducibly construct the alleged “biological material” of the cartridges and vectors of Claim 10, 12-13 and 17, in accordance with the enablement requirement of 35 U.S.C. 112, first paragraph.

D. Response to Rejection of Claims 1-8, 15 and 18-19 under 35 U.S.C. 102(b), as Anticipated by Cary et al

At pages 6-7 of the Office Action, Claims 1-8, 15 and 18-19 have been rejected under 35 U.S.C. 102(b) as being anticipated by the article to Cary *et al.*

Referring to Figures 2 and 5, the Office Action alleges that Cary *et al.* teaches a DNA molecule comprising the entire *piggyBac* (*i.e.*, IFP2) molecule, including a right terminal repeat, a right internal repeat, a left internal repeat and a left terminal repeat. Referring to Figure 5, the Office Action alleges that the total length of the *piggyBac* molecule taught by

Cary *et al.* is 2475 nucleotides. Accordingly, the Office Action says that the *piggyBac* molecule taught by Cary *et al.* comprises at least 276 consecutive nucleotide base pairs of the 3' terminal region beginning at the 3' terminal base pair and at least 172 consecutive nucleotide base pairs of the 5' terminal region beginning at the 5' terminal base pair.

Applicants respectfully traverse this rejection. Responsive to this rejection, Claims 1-8 have been rewritten as new Claims 20-27:

1. Claims 20-22 define a DNA molecule comprising a minimal transposable *piggyBac* genetic construct having a spacer (of at least 40 nucleotide base pairs) and at least one 5' and 3' minimal sequence (comprising a TTAA target site and 35 or 63 nucleotide base pairs of the respective terminal repeat domain of the *piggyBac* molecule) adjacent to at least one end of the spacer. Cary *et al.* does not teach or suggest the minimal transposable *piggyBac* genetic construct of Claims 20-22 comprising the spacer (as defined) and having at least one 5' and 3' minimal sequence (comprising the target site and base pairs of the respective terminal repeat domain as defined) adjacent to least one end of the spacer. Claim 18, which now depends from Claim 23, is also not taught or suggested by Cary *et al.* for the same reason.
2. Claims 23-27 define a DNA molecule comprising a minimal transposable *piggyBac* genetic construct having the spacer and at least one 5' and 3' minimal sequence (comprising a TTAA target site, 35 or 63 nucleotide base pairs of the respective terminal repeat domain of the *piggyBac* molecule, and more than 66 or at 172 nucleotide base pairs of the respective adjacent internal domain sequence of the *piggyBac* molecule) adjacent to at least one end of the spacer. Cary *et al.* does not teach or suggest the minimal transposable *piggyBac* genetic construct of Claims 23-27 comprising the spacer (as defined) and having at least one 5' and 3' minimal sequence (comprising the target site, as well as the base pairs of the respective terminal repeat domain and adjacent internal domain sequence as defined) adjacent to least one end of the spacer) adjacent to least one end of the spacer. Claims 15 and 19, which now depend from Claim 23, are also not taught or suggested by Cary *et al.* for the same reason.

New Claims 28-32 have also been added which define a transposable genetic construct comprising a DNA molecule to be transferred flanked by a pair of transposon terminal inverted repeat nucleotide sequences from the *piggyBac* transposon. This pair of transposon terminal inverted repeat nucleotide sequences are defined as being either a pair of: (1) 5' minimal sequences comprising a TTAA target site, the 35 nucleotide base pairs of the 5' terminal repeat domain of the *piggyBac* molecule, and optionally more than 66 nucleotide base pairs of the adjacent 5' internal domain sequence of the *piggyBac* molecule; or (2) 3' minimal sequences comprising a TTAA target site, the 63 nucleotide base pairs of the 3' terminal repeat domain of the *piggyBac* molecule, and optionally at least 172 nucleotide base pairs of the adjacent 3' internal domain sequence of the *piggyBac* molecule. Cary *et al.* does not teach or suggest a transposable genetic construct comprising a DNA molecule to be transferred that is flanked by the pair of transposon terminal inverted repeat nucleotide sequences as defined in Claims 28-32.

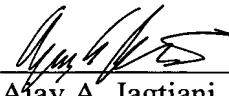
For at least the foregoing reasons, Claims 15, 18-19 and 20-32, are novel and unobvious over Cary *et al.*

E. Conclusion

In conclusion, new Claims 20-27 define statutory subject matter under 35 U.S.C. 101. New Claims 20-27, as written, as well as Claims 14-15 and 18-19, as amended, comply with the requirements of 35 U.S.C. 112, second paragraph. The cartridges and vectors of Claims 10, 12-13 and 17 are enabled in accordance with 35 U.S.C. 112, first paragraph. Claims 15, 18-19 and 20-32, are novel and unobvious over the art relied on in the Office Action.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited. If the Examiner has any questions or concerns regarding the present amendment, the Examiner is invited to contact Eric W. Gutttag at 703-591-2664, Ext. 2012.

Respectfully submitted,



Ajay A. Jagtiani
Reg. No. 35,205

JAGTIANI + GUTTAG
Democracy Square Business Center
10363-A Democracy Lane
Fairfax, Virginia 22030
703-591-2664

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Amendments to the Drawings:

The attached one (1) sheet of drawings includes changes to FIG. 26. This sheet replaces the original sheet including FIG. 26. In Figure 26, the reference character "c" as described in the brief description of the drawing was omitted.